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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,142	11/09/2000	Alessandra Pavesio	515-4210	1911

7590

11/06/2002

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EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 11/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,142

Applicant(s)

PAVESIO ET AL.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on the election of species of 19 AUG 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 24-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Status of Claims

1. Claims 1 and 24-35 are pending.
2. Claim 1 and 24-35 are rejected.

Election/Restrictions

3. Applicant's election with traverse of the species of Group (a) in Paper No. 6 is acknowledged. The traversal is on the ground(s) that there is a technical relationship shared by the individual Groups of hyaluronic acid ester derivatives. This is not found persuasive because each of these individual Groups of hyaluronic acid ester derivatives are not linked as to form a single general inventive concept due to the litany of groups, such as cross-linked esters, hemiesters of succinic acid and N-sulfated derivatives of hyaluronic acid ester, which can be derivatized to the hyaluronic acid moiety.
4. The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

5. The information disclosure statement filed on November 9, 2000 has been reviewed and considered, see enclosed copy of PTO FORM 1449.

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Drawings

6. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

7. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a

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nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 begins with the non-statutory phrase of, "Use of" However, in order to expedite prosecution, this claim will be treated as a Method of use claim.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 1 provides for the use of at least one hyaluronic acid derivative, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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12. Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

13. Claim 1 is rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph. The claim(s) are narrative in form and replete with indefinite and functional or operational language. The claim must be in one sentence form only.

14. Claims 26-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of these claims is dependent on cancelled claim 23. Consequently, these claims are vague and indefinite.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claim 1 and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dorigatti et al. of WO 93/11803. Dorigatti et al. teach of biocompatible non-woven fabric biomaterials for use in surgery and specifically for the regeneration of tissues. In

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addition, Dorigatti et al. teach that these biomaterials are comprised of esters of hyaluronic acid with aliphatic, araliphatic, cycloaliphatic, or heterocyclic alcohols, (see pages 7 and 8). Furthermore, Dorigatti et al. disclose that this biomaterial of the partial esters of hyaluronic acid ester have less than 85% of the groups esterified. In fact, Dorigatti et al. teach that 50% of the carboxylic acid groups are esterified in Example 1, (see pages 18-19) and 75% of the carboxylic acid groups are esterified in Example 7, (see page 24) and that 85% of the carboxylic acid groups are esterified in Example 15, (see pages 27-28). Dorigatti et al. also teach of the benzyl esters of hyaluronic acid in Example 12, (see page 26). Furthermore, this prior art invention is directed to use in a variety of surgical procedures, namely orthopedics, (see pages 39 and 40).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 1 and 24-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorigatti et al. of WO 93/11803. Dorigatti et al. teach of biocompatible non-woven fabric biomaterials for use in surgery and specifically for the regeneration of tissues. In addition, Dorigatti et al. teach that these biomaterials are comprised of esters of hyaluronic acid with aliphatic, araliphatic, cycloaliphatic, or heterocyclic alcohols, (see pages 7 and 8). Furthermore, Dorigatti et al. disclose that this biomaterial of the partial esters of hyaluronic acid ester have less than 85% of the groups esterified. In fact, Dorigatti et al. teach that 50% of the carboxylic acid groups are esterified in Example 1, (see pages 18-19) and 75% of the carboxylic acid groups are esterified in Example 7, (see page 24) and that 85% of the carboxylic acid groups are esterified in Example 15, (see pages 27-28). In addition, the prior art reference of Dorigatti et al. do not claim nor teach of the incorporation of cellular components, (see claims 1-29). Dorigatti et al. also teach of the benzyl esters of hyaluronic acid in Example 12, (see page 26). Furthermore, this prior art invention is directed to use in a variety of surgical procedures, namely orthopedics, (see pages 39 and 40). Even though Dorigatti et al. do not specifically teach of excluding cellular components and products in these biomaterials of hyaluronic acid ester, it is noted that Dorigatti et al. do not teach in this patent of including cellular components and products in this biomaterial of esters of hyaluronic acid. Clearly, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize the teachings of Dorigatti et al. to arrive at the instant

get rid of claims for claims 1

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invention because Dorigatti et al. do not disclose of including cellular components and products in this biomaterial of esters of hyaluronic acid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
November 5, 2002